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14. ABSTRACT

The Windber/Walter Reed Clinical Breast Care Project will help lead the way in the 21st Century in the crusade against breast disorders. The project will utilize a multidisciplinary approach as the standard of care for treating breast diseases and breast cancer. Thus multidisciplinary model integrates prevention, screening, diagnosis, treatment and continuing care, but the project is further unique in the incorporation of advances in risk reduction, informatics, issue banking and research. These efforts will focus on decreasing the morbidity and mortality of breast cancer among American women.

15. SUBJECT TERMS
Tissue banking, Biomedical Informatics, Focused Research, Translational Research, Genomics, Proteomics, Risk Reduction, Comprehensive Breast Care, Vaccine Development

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Comprehensive Reproductive System Care Program—Clinical Breast Care Project (CRSCP-CBCP)
Annual Report

1. INTRODUCTION:

The Clinical Breast Care Project (CBCP) is the outcome of the initial FY00 and subsequent Congressional appropriations, and consists of an extensive collaborative effort between Windber Medical Center (Windber, PA – 12th Congressional District of the Honorable John P. Murtha) and Walter Reed Army Medical Center, with funding management by the Henry M. Jackson Foundation for the Advancement of Military Medicine. "The Clinical Breast Care Project (CBCP)" moniker is modified to more reflect its expanded congressional mission, and in FY05 became officially entitled, "The Clinical Breast Care Project of the Comprehensive Reproductive System Care Program". In correspondence, conversation and general usage the shortened form is the "CBCP (of the CRSCP)".

Ultimate Goal of this project: Decrease morbidity and mortality of breast cancer among American Women. Through the interlacing of the five pillars, the CBCP will help lead the crusade against breast disorders.

- Develop a comprehensive breast care center/system to enable health care providers with a multidisciplinary team approach that works towards the common goal.
- Empower women with breast cancer and other breast disorders with the decision-making tools and environment to enhance quality of life and to meet psychosocial needs of the patients and their families.

The five pillars of the CBCP of Walter Reed/Windber are (1) Risk Reduction (2) Focused Research (Genomics and Proteomics; and breast cancer vaccine development); (3) Tissue banking ; (4) Biomedical informatics; and (5) Clinical Care;.

Pillar Specific Objectives:

1. ***Risk Reduction***:
    - Identify the population of patients at above average risk for the development of breast cancer.
    - Decrease this identified population's rate of breast cancer development.
    - Analyze potential cost differential in the prevention of breast cancer development.
2. ***Focused Research***:
    - Utilize our CBCP-developed panel of microsatellite chromosomal markers to genomically assess various stages of breast disease, malignant and

benign, in our on-going effort to elucidate the biologic development timeline of breast cancer.

- Analyze our in-depth serum and blood repository utilizing various proteomic identification and pattern technologies in our ongoing effort to identify new biomarkers that can be predictive of breast cancer risk and development.
- Utilize our microarray gene expression profiling capabilities in our effort to analyze the gene expression changes of the continuum of breast disease and cancer development.
- Analyze the relationship of certain breast cancer protein aspects, eg. ORP-150 protein, to prognosis and other known variables of breast cancer biology.
- Development and Clinical Testing of Adjuvant Vaccines—Develop a HER-2/neu vaccine. Assess safety and document local and systemic toxicity to the HER-2/neu peptide. Determine maximum tolerate dose (MTD) and optimal biologic dose (OBD). Evaluate the in vivo cellular immune response to the peptide vaccine. Evaluate time to recurrence in the vaccinated patients vs. matched controls.

3. ***Tissue Bank***:
    - Collect and store specimens of breast tissues, lymph nodes, bone marrow aspirates, serum, blood cells (leukocytes), and plasma from every patient undergoing a breast biopsy and/or breast surgery at WRAMC, WMC, MGMC, and LRMC who consent to participate in this study. Use the power of this tissue bank to dramatically further breast disease research.
4. ***Bio-Informatics***:
    - Develop and implement a clinically-relevant prospective, longitudinal computerized database for use in patients with all types of breast care needs.
    - Link this database information through the Internet to data set at a rural primary breast care center with appropriate security and firewall protections.
    - Develop the database to allow for "on-the-fly," relational, clinically-relevant statistical analysis.
    - Develop an informatics companion to the prospective serum / breast tissue bank. (Pillar 3)
5. ***Clinical Care***:
    - Decrease the negative psychological impact on the patient of having an evaluation or treatment intervention for breast disease.
    - Create and maintain an environment (medical, physical, psychological) conductive to the multiple needs of the patient undergoing breast disease evaluation / treatment.
    - Utilize objective measurement instruments to longitudinally assess the patient's psychological response to evaluation and intervention, and base modifications on those results.

Summary of the methodology of the project.
The five pillars of the CBCP of Walter Reed/Windber are (1) Clinical Care; (2) Tissue banking; (3) Risk Reduction; (4) Biomedical informatics; and (5) Focused research (Genomics and Proteomics; and breast cancer vaccine development).

- The clinical care pillar was established by building state of the art breast care facilities at the Windber and Walter Reed sites. These sites were critical to the ability to implement all other pillars of this Project. The Walter Reed Comprehensive Breast Center opened in July 2001, and the Joyce Murtha Breast Center in Windber opened in February 2002.

- The tissue banking pillar was established at both sites in collaboration and entails acquisitions, storage, and movement amongst the sites for research purposes of tissue garnered from all breast surgeries being preformed at both locations. The robust IRB-approved protocol that enables this pillar is unique in four critical aspects: It is a tissue usage protocol, not a repository one; It is hypothesis-generating, not hypothesis-driven research; It allows for patients to pre-consent for secondary, future uses of the tissues in presently-unknown research; It contains a unique fail-safe mechanism to protect the complete diagnostic integrity of all samples.

- The informatics piece is resulting in a mutual Walter Reed and Windber collaborative development of a high-end breast disease database, which is a resource for all investigators and is exportable for use by other investigators, programs, and organ sites. The database uniquely integrates clinical data with genomic and proteomic analysis of patient samples and is being extended to incorporate an image repository. This is being developed in close collaboration with leading industry leaders in the high-end database field, specifically NCR (National Cash Registry, Inc.) and Cimarron Software Developers. Extensive efforts to model the pathways of breast cancer and its risk factors are underway at Windber with consultation from Walter Reed.

- The risk reduction pillar is a vital portion of this mutual project which has resulted in the capability of the project to establish a screening program to identify women who are at high risk of developing breast cancer, and to enter them into a very time- and resource-intensive risk reduction program which can only be appropriately resourced through an appropriation such as this, to decrease significantly these patients' chance of getting breast cancer in the future.

- The research aspect is centered on functional genomic/microarrays/proteomics analysis of the tissues and biospecimens, which are acquired as described above. The

collaborative research on the functional genomics is established through a high-end microarray, genomics, and proteomics facility at the CBCP Windber Research Institute and will be used as the prime research center for the tissue collaborations, which are developed through this project. Additionally, CBCP is involved in some aspects of breast cancer vaccine research, with both Windber and Walter Reed clinical sites having mutually and cooperatively set-up the breast cancer vaccine program and that is now being offered at both sites.

- An important outgrowth of this effort is and will be the bringing of more patients into the Windber and Walter Reed sites for breast cancer evaluations and treatment options; also, the economic development at Windber is being enhanced through job creation and establishment of the scientific research center.

2. BODY:

The CBCP established six primary tasks in its approved Statement of Work for the 2005 fiscal year. These six tasks consist of:

- Task 1. Enroll over 500 patients annually to the "Core" CBCP protocols through consenting in the main CBCP clinical sites.
    a. Core protocols of Tissue and Blood acquisition and molecular testing at the DNA, RNA and Protein level, allied with the clinical and demographic databases.
    b. Affiliated protocol accrual to the node-negative and node-positive breast cancer vaccine Phase Ib trial (accrue no less than 30 patients annually).
- Task 2. Continuing molecular analysis in CBCP labs, as outlined in the CBCP Core Protocols allowing for global expression analysis of the DNA, RNA and Protein features.
- Task 3. Continue software development of the CLES (Clinical Laboratory Workflow System) and its further deployment as a Beta version into the clinical/research arms of the CRSCP-CBCP within 12 months.
- Task 4. Identifying and counseling no less than 100 high risk patients for development of breast cancer and employ risk reduction strategies.
    a. Perform BRCA gene mutation testing on 10 patients annually in contract with MYRIAD Genetics.
- Task 5. Performing targeted research into genomic analysis of Stages I, II, and III breast cancer, DCIS, LCIS and pre-malignant neoplasia, and presenting findings at national meetings and in peer-reviewed publications.
- Task 6. Perform mass spectrometry fingerprinting of 200 sera samples from patients with diagnosis of breast diseases and analyze for distinct patterns based on disease state.

In the 1st Quarter, reporting period 21 April – 20 July 2005, the Clinical Breast Care Project (CBCP) was provided funding on 20 April 2005; however the original Grant through the Uniformed Services University did not expire until 31

July 2005. The project commenced utilization of MRMC Grant funds the mid part of June. The personnel expenditures started on 26 June; while the Supply and travel expenditures were for events and items that were to occur in August and after which could not be charged against the FY 04 USU funds.

Task 1: Enrolling over 500 patients in the "core" CBCP protocols.
See section 5 Reportable Outcomes for the breakdown and number of subjects enrolled in "core" CBCP protocols.

Task 2: Continuing molecular analysis in CBCP labs, as outlined in the CBCP Core Protocols allowing for global expression analysis of the DNA, RNA and Protein features. A new organizational plan at the CBCP labs at WRI allowed for more efficient identification of samples to be parallel-processed. As a result, core organizational assets of DNA, RNA, and protein analysis became more robust. This ongoing effort resulted in approximately 200 samples undergoing broad analysis on a molecular level. For FY 2005, **505** donors contributed **5,488** samples. As it is resource-intensive to perform comprehensive molecular profiling even in a project such as CBCP, and cost-prohibitive to perform the comprehensive (DNA, RNA, Protein levels) on all CBCP samples (especially since our success in accruing patients has been so extensive, resulting in our far exceeding our goals for annual specimen acquisitions for the tissue repository), CBCP instead performs certain analyses on important subsets of samples of compelling research interest, and the "global" profiling across the entire Central Dogma (DNA, RNA, Protein) on a different selected subset, in order to maximize efficiencies and appropriately utilize monetary and equipment resources.

Task 3: Continuing software development of the CLWS (Clinical Laboratory Workflow System) and its further deployment into the clinical/research arms of the CRSCP-CBCP. During the last year, a standard operating procedure (SOP) for data entry and quality assurance (QA) of the questionnaire data has been established. The current QA measures for clinical data include, visual inspection by the data entry clerk, double blind-data entry, and a computer program checking applying all the QA rules that have been developed to examine the data integrity within and between data fields. A QA issue tracking (QAIT) system has also been developed and implemented, which dramatically improved the communications on QA issues between the WRI data entry group and the Walter Reed questionnaire QA team.

With the belief that electronic data capturing will enhance clinical data collection and precision, WRI has taken the initiative in developing a prototype tablet application using the Pathology Checklist as the first example following a decision made at the last CBCP Offsite meeting. This prototype is under further evaluation at both WRI and Walter Reed before a full-blown development starts.

The data warehouse development has further evolved to provide data and analytical support to CBCP research, which is done by collaborating with leading data

management and analysis companies such as InforSense and Concentia Digital. An On-Line Analytical Processing (OLAP) tool has been developed to allow for easy access and stratification of hundreds of data elements across thousands of subjects enrolled in CBCP. A 'patient view' tool has been developed to allow for exploration of warehoused data from an individual patient. An application prototype has been developed to enable users to access clinical or experimental images at ease with a built-in robust data-element filtering capability. All these translational research-enabling applications will be migrated to and further developed on a newly designed patient-centric, object-oriented data model with a temporal dimension. We expect that this newly designed data model, which is in the process of being implemented, will dramatically enhance our translational research capability when compared to the old questionnaire-based data structure.

Task 4: Identifying and counseling high risk patients for development of breast cancer and employ risk reduction strategies. The risk reduction pillar is a vital portion of this mutual project which has resulted in the capability of the project to establish a screening program to identify women who are at high risk of developing breast cancer, and to enter them into a very time- and resource-intensive risk reduction program which can only be appropriately resourced through an appropriation such as this, to decrease significantly these patients' chance of getting breast cancer in the future.
More than 200 patients were entered into the program this year. The extensive risk assessment, family history and pedigree generation, computerized modeling of individual risk, genetic mutation testing when appropriate (BRCA-1 and BRCA-2), implementation and follow-up of intervention strategies to include chemoprevention, novel diagnostic testing, and even surgical prophylaxis, resulted in a highly successful program where breast cancer truly is being prevented before it ever occurs in many women.

Task 5: Performing targeted research into genomic analysis of Stages I, II, and III breast cancer, DCIS, LCIS and pre-malignant neoplasia, and presenting findings at national meetings and in peer-reviewed publications during FY05. CBCP has been tremendously successful in this regard this year as well. We have verified that important genetic changes occur across multiple chromosomal regions as breast epithelium transitions from non-neoplastic into neoplastic types. We have identified these changes and published the specific markers for chromosomal loci that are modified as a requirement for, or as a result of, the malignant transformation process. We are deciding now as an organization whether to seek patent protection for this panel of markers, which may be consider a diagnostic and prognostic marker panel for breast cancer and breast cancer development. See ATTACHMENT 2.

Task 6: Perform mass spectrometry fingerprinting of 200 sera samples from patients with diagnosis of breast diseases and analyze for distinct patterns based on disease state.

Using over 600 CBCP sera samples, we have undertaken a set of proof of principle experiments to show there is sufficient information in serum to diagnose the presence or absence of breast cancer. We hypothesize that there are molecular patterns in serum that are unique to breast cancer. These patterns are composed of multiple (3 or more) molecules, which by themselves are not informative, but when taken together, and measured relative to each other, are informative.

Our approach is to profile sera using high-resolution mass spectrometry, and then apply a novel, patented pattern recognition algorithm to these data, to identify patterns that can distinguish the sera from women with breast cancer, from women without breast cancer.

In 2005 we presented a poster at ASCO reporting our first results. Using sera from women representing 67 cases of *in situ* carcinoma, 195 invasive carcinoma, and 350 normal/benign breast conditions, we identified several informative serum patterns with sensitivities and specificities in the range of 80 – 90% on a blinded validation set. One profile, consisting of 10 serum features, yielded 98.5% specificity (95% CI 95.2 – 99.6%) and 90.3% sensitivity (95% CI 82.4 – 95%) on a Testing set of 196 non-malignant sera and 103 invasive sera. When this pattern was challenged with a Blinded Validation set of 54 non-malignant and 41 invasive sera we observed 92% specificity (95% CI 74.5 – 93.6%) and 86% sensitivity (95% CI 76.4 – 97.8%).

With such studies there are two significant concerns – sample set bias and overfitting of data. Recently, using an expanded set of sera now representing 454 women with invasive cancers, we performed an extensive analysis of the data to minimize sample set bias, and implemented an algorithm to monitor for overfitting of data. We identified several serum patterns that distinguished between invasive cancer and normal/benign, non-neoplastic conditions. Performance was 85% sensitivity (standard deviation ± 7%) and 82% sensitivity (standard deviation ±10%). While a little lower than the first study, these results are considerably more robust.

These unpublished proof of principle results show that serum does contain sufficient information to distinguish between the presence and absence of breast cancer. As our serum set increases in size, and our algorithm experiences a greater extent of the variability of the disease within the population, we anticipate the performance should improve significantly.

3. ADDITIONAL ACCOMPLISHMENTS

Coordination of the expansion of the CBCP to Anne Arundel Medical Center, Annapolis, MD took place this year in order to further the acquisition of breast tissue, blood/serum samples, and accompanying data variables for the CBCP Biorepository for research purposes. In the 1st Quarter a contract was awarded to Anne Arundel Medical Center, Annapolis, MD. AAMC submitted their protocol for review to their IRB. In the 2nd Quarter the protocol was approved by the AAMC IRB and forwarded to the MRMC ORP for secondary review. In the 3rd

Quarter the protocol was in the review process with MRMC ORP and in the 4th Quarter secondary approval was received. The AAMC research nurse was oriented at WRAMC and at Malcolm Grow Medical Center on Andrews Air Force Base and an overview and orientation for AAMC key players was conducted at WRAMC. The WRAMC Pathologist and Pathologist Assistant traveled to Anne Arundle to conduct an orientation for the AAMC pathologists. In the next quarter we expect that Anne Arundel Medical Center will be fully operational as a CBCP partner and actively contributing to the CBCP biorepository.

The CBCP conducted the 6th Annual CBCP Offsite 14-16 November 2005. Current state of research was presented, and the Scientific Advisory Board Meeting and strategic planning was conducted during the sessions.

The project with InforSense to create an **O**n-**L**ine **A**nalytical **P**rocessing (OLAP) tool for accessing the CBCP data, moved forward smoothly as scheduled. In the previous reporting quarter, a pre-beta version was released to the Biomedical Informatics group and the CBCP leaders in both Walter Reed Army Medical Center and the Windber Research Institute. This was followed by a beta version release to the whole Windber Research Institute and a couple other organizations. Based on the feedback of the pre-beta and beta tests from the Windber Research Institute, the Walter Reed Army Medical Center, and the Military Cancer Institute, the software was further improved with a major upgrade and the first production version was released to the CBCP on April 17, 2006.

4. KEY RESEARCH ACCOMPLISHMENTS

- Continued to build the world's largest and best-characterized biospecimen repository of breast disease specimens, now numbering over 20,000 total specimens on over 2,500 enrolled research patients.
- Identified, characterized, and verified the chromosomal changes that occur during the progression of breast tissue from benign to early malignant disease.
- Developed an albumin-depletion methodology for the proteomics analysis of serum samples that was critical to our ability to find important low-abundance proteins and peptides that are found in the bloodstream of patients with breast cancer (i.e., an important step in developing a "breast cancer blood test").
- Implemented the working version of the database and data warehouse system that CBCP has been developing for four years, that integrates the clinical, molecular, pathologic, and biorepository aspects of CBCP translational research, along with robust query capability and analysis tools.
-

5. REPORTABLE OUTCOMES

The CBCP Research Protocols and number of subjects recruited to each for the period June 1 2005 to June 30 2006 is as follows:

Clinical Breast Care Project Walter Reed Army Medical Center

a. Creation of a Blood Library for the Analysis of Blood for Molecular Changes Associated with Breast Disease and Breast Cancer Development - **159**
b. Tissue and Blood Library Establishment for Molecular, Biochemical and Histologic Study of Breast Disease - **303**
c. Molecular Phenotyping of Bone Marrow Aspirates and Peripheral Blood Collected As Part of The Walter Reed Army Medical Center Clinical Breast Care Project (CBCP) – **39**
d. Phase 1b Trial of HER2/neu Peptide (E75) Vaccine in Breast Cancer Patients at High Risk for Recurrence after Surgical and Medical Therapies - **68**
e. Phase 1b Trial of HER2/neu Peptide (E75)Vaccine in Node Negative Breast Cancer Pts. – **41**
f. Phase 1b Trial of HER2/neu Peptide (GP2) Vaccine in Breast Cancer Patients – **5**
g. Phase 1b Trial of HER2/neu Hybrid Peptide (AE37) Vaccine in Breast Cancer Pts. – **17**
h.

The Windber Joyce Murtha Breast Care Center Research Protocols and subjects recruited to each is as follows:

i. Creation of a Blood Library for the Analysis of Blood for Molecular Changes Associated with Breast Disease and Breast Cancer Development - **11**
j. Tissue and Blood Library Establishment for Molecular, Biochemical and Histologic Study of Breast Disease - **51**
k. Phase 1b Trial of HER2/neu Peptide (E75) Vaccine in Breast Cancer Patients at High Risk for Recurrence after Surgical and Medical Therapies – **12**
l. Phase 1b Trial of HER2/neu Peptide (E75)Vaccine in Node Negative Breast Cancer Pts. – **20**

The Malcolm Grow Medical Center Research Protocols and subjects recruited to each is as follows:

m. Creation of a Blood Library for the Analysis of Blood for Molecular Changes Associated with Breast Disease and Breast Cancer Development- **73**
n. Tissue and Blood Library Establishment for Molecular, Biochemical and Histologic Study of Breast Disease - **23**

The Landstuhl Regional Medical Center Research Protocols and subjects recruited to each is as follows:

o. Creation of a Blood Library for the Analysis of Blood for Molecular Changes Associated with Breast Disease and Breast Cancer Development- **64**

A dedicated psychologist counsels 20-40 patients on an ongoing or crisis basis and sees all diagnosed breast cancer patients attending our Friday template.

A list of presentations, publications and abstracts is provided as attachment 1.

6. CONCLUSIONS

The next great advances in breast cancer prevention and treatment will be based upon an increased understanding of the changes that occur in the normal breast tissue cells, as they transition into cancer cells. The CBCP, through its unique and inter-connected 5 pillars, leverages the strengths of its clinical care arm and connects it to a research arm that studies these cells as they change into cancer. To date, we have been the first to show that the way that breast cancer "behaves", is possibly pre-determined very early in the change of the cells as they are becoming cancerous, as opposed to the cancer cells getting "worse" as they grow and develop. In other words, our important findings are indicating that the behavior of the cancer cells is determined right when the cells are developing, not later. The implications of these findings are critical in our understanding of breast cancer biology, and are leading to new understanding in developing prevention strategies and treatment programs.

Our tissue repository has grown into the world's largest and best characterized (annotated) biorepository of human breast tissues, receiving great acclaim from research organizations around the world, and is being shared with other research organizations of great renown, in an effort to speed the pace of discoveries through sharing of this irreplaceable resource.

We are finalizing our study into whether or not we can identify "the breast cancer blood test", through the use of of serum repository, linked to one of the world's foremost organizations capable of identifying protein patterns in serum for various organ system cancers.

Medical/military significance: Nearly 20% of the Active Duty Army Force is female, so breast health issues are a significant force protection issue for the US military. In addition, the majority of the remaining male Active Duty members are married, and the healthcare of family members is always at the top of the priority list on surveys of active duty members. Breast health issues and breast cancer detection, research, and treatment, are taking on a greater urgency to maintain the health and morale of the Army. The Comprehensive Breast Center at Walter Reed, which opened on July 31, 2001, is the U.S. Army's first and only stand-alone Breast Center, being a state-of-the-art facility incorporating the finest technology and research with a warm and welcoming atmosphere of caring.

In summary the Clinical Breast Care Project, a collaborative effort between Walter Reed and Windber, has resulted in excellent working relationships and collaborations between the two sites on all five of the project's main pillars. The project is achieving its goals and looks forward to further continuance of this great vision and what will be a national resource, into the future.

7. REFERENCES

N/A

8. APPENDICIES

See page 7 of instructions - attach all appendices that contain information that supplements, clarifies or supports the text.

- ATTACHMENT 1 List of publications and meeting abstracts for FY 2005
- ATTACHMENT 2 :List of personnel receiving pay from the research effort in FY05

ATTACHMENT 1

PUBLICATION, ABSTRACT AND PRESENTATION DATA

June 1, 2005 – June 30, 2006

PRESENTATIONS - 2005
1) 1.Bukowski, V., Maity, T., Kolli, K., Kirchner, D., Brzeski, H., Liebman, M., Shriver, C., & Keeney, J. "Optimization of Gel Filtration Chromatography for High Molecular Weight Protein Separation in Human Serum (Poster Presentation)", Poster Presentation at the Showcase for BioTechnology 2005, Johnstown, PA.
2) Ellsworth, D. "Molecular Alterations in Tumor-Adjacent Normal Tissues: Implications for Defining Tumor-Stromal Interactions [Oral Presentation]", 6th Annual CBCP Offsite Meeting, November 13 - 16, 2005, Cumberland, MD.
3) Ellsworth, R., Ellsworth, D., Deyarmin, B., Patney, H., Hooke, J., & Shriver, C. "HER2 Gene Amplification is a Maarker for Blobal Genomic Instability", Presentation at the Showcase for BioTechnology, Johnstown, PA
4) Ellsworth, R., Ellsworth, D., Love, B., Hoffman, L. R., Deyarmin, B., Hooke, J., & Shriver 2005d, "Genomic Alterations as a Pathological Aid to Classifying Ductal Carcinoma In-Situ [Poster Presentation]", Poster Presentation at the San Antonio Breast Cancer Symposium, December 8 - 11, 2005.
5) Ellsworth, R., Leach, R., Hoffman, L., Snyder, C., & Lynch, H. "Identification of Genetic Modifieres in a Large BRCA1 Family. [Poster Presentation]", American Society of Human Genetics 55th Annual Meeting, October 2005.
6) Field, L. "Breast Cancer in African American and Caucasian Women", Penn Highlands Community College.
7) Field, L. "Identification of Molecular Changes Associated with Breast Tumor Phenotype in African American Women [Oral Presentation]", 6th Annual CBCP Offsite Agenda, November 13 - 16, 2005, Cumberland, MD.
8) Field, L., Bradley L, Kane, J., Deyarmin, B., Hooke, J., Ellsworth, R., & Shriver, C. 5 A.D.a, "Gene Expression Differences in Disease-Free Breast Tissue in African American Women Versus Caucasian Women [Poster Presentation]", Poster Presentation at San Antonio Breast Cancer Symposium, San Antonio, TX, December 8 - 11, 2005.
9) Field, L., Love, B., Kane, J., Deyarmin, B., Hooke, J., Ellsworth, R., & Shriver, C. "Identification of Molecular Changes Associated with Breast Tumor Phenotype in African American Women", Presentation at the Showcase for BioTechnology 2005, Johntown, PA.

10) Guo, X., Shriver, C., Hu, H., & Liebman, M. "Semantic Similarity-Based Validation of Human Protein-Protein Interactions (Poster Presentation)", Stanford,CA.
11) Hu, H. "Biomedical Informatics at Windber Research Institute [Oral Presentation]", 6th Annual CBCP Offsite Meeting, November 13 - 16, 2005, Cumberland, MD.
12) Hu, H. "Biomedical Informatics Research and Development at Windber Research Institute", Presentation at the Showcase for BioTechnology 2005, Johnstown, PA.
13) Hu, H. "Data Warehouse and Analytical Portal Development - Introducing an OLAP Clinical Data Analysis Tool [Oral Presentation]", 6th Annual CBCP Offsite, November 13 - 16, 2005, Cumberland, MD.
14) Kaufman, M., Brzeski, H., Maity, T., & Liebman, M. "Pcr Amplification of a Cpg Island in the Prdm15 Gene Prior to Developing a Hypermethylation Assay for Genes Deregulated in Breast Cancer (Poster Presentation)", Poster Presentation at the Showcase for BioTechnology 2005, Johnstown, PA.
15) Maskery, S. "Co-Occurrence Analysis for Discovery of Novel Breast Cancer Pathology Patterns [Oral Presentation]", 6th Annual CBCP Offsite Meeting, November 13 - 16, 2005, Cumberland, MD.
16) Maskery, S., Tsavachidou, D., & Liebman, M. "Modeling and Simulation of the Perimenopause Transition [Poster Presentation]", North American Menopause Society 16th Annual Meeting, San Diego, CA, September 28 - October 1, 2005.
17) Maskery, S., Zhang, Y., Hu, H., Hooke, J., Shriver, & Liebman, M. "Variation in Breast Disease Co-Occurrence Frequencies Between Pre- and Post- Menopausal Women [Poster Presentation]", Poster Presentation at the 28th Annual San Antonio Breast Cancer Symposium, December 8 - 11, 2005 in San Antonio, TX.
18) Maskery, S., Zhang, Y., Hu, H., Shriver, C., Hooke, J., & Liebman, M. "Breast Disease Profiles in Pre- and Post-Menopausal Women [Poster Presentation]", North American Menopause Society 16th Annual Meeting, San Diego, CA September 28 - October 1, 2005.
19) Maskery, S., Zhang, Y., Jordan, R., Hu, H., Shriver, C., Hooke, J., & Liebman, M. "Bayesian and Non-Bayesian Computational Analyses of Heterogeneity in Breast Disease, A Case Study in Datamining Clinical Records for Disease Hypothesis Generation", Presentation at the Showcase for BioTechnology 2005, Johnstown, PA.
20) Ru, Q. "Comprehensive Sera Profiling of Breast Cancer vis LC-MS Based Proteomicvs Platform [Oral Presentation]", 6th Annual CBCP Offsite Meeting, November 13 - 16, 2005, Cumberland, MD.
21) Ru, Q. "Comprehensive Serum Proteome Profiling of Breast Cancer with the Application of Multi-Dimensional Protein Identification Technology", Keynote Oral Presentation Life Science, BCEIOA 2005, Beijing, China, October 22, 2005.

22) Ru, Q., Zhang, L., Silberman, J., Liebman, M., Jacobs, N., & Shriver, C. 5 A.D.a, "Peptide Breast Cancer Biomarkers Detectable Through Blood Tests [Poster Presentation]", Poster Presentation at San Antonio Breast Cancer Symposium, San Antonio, TX, December 8 - 11, 2005.

23) Ru, Q., Zhu, A., Zhang, Y., Silberman, J., Brzeski, H., Liebman, M., & Shriver, C. "Comprehensive Serum Proteome Profiling of Breast Cancer with the Application of Multi-Demensional Protein Identification Technology (Poster Presentation)", Poster Presentation at the Showcase for BioTechnology 2005, Johnstown, PA.

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ATTACHMENT 2

CBCP PERSONNEL RECEIVING PAY FROM THE RESEARCH EFFORT IN 2005

Last Name	First Name	Role	Percent of Effort
Shriver	**Craig**	**Principal Investigator**	**25%**
Allen	Peter	Breast Surgeon	25%
Baker	Benjamin	Lab Assistant	100%
Basham	Janice	Licensed Practical Nurse	100%
Bauchiero	Samantha	Research Assistant	100%
Bronfman	Eileen	Protocol Coordinator	100%
Chestang	Allan	Data Manager	100%
Cooper	Leslie	Psychologist	100%
Del	Ismail	Data Manager	100%
Fantacone	Jamie Leigh	Pathology Assistant	100%
Glasco	Tiffani	Administrative Clerk	100%
Gutchell	Veronica	Head Nurse, CBCP/ Nurse Pract.	100%
Hamsher	Carlyle	Research Assistant	100%
Hapner	Arthur	Executive Director & COO	100%
Harris	Katie	Research Assistant	100%
Hearrell	Elizabeth	Research Nurse	100%
Hooke	Jeffrey	Head of Pathology	100%
Jama	Yusuf	Research Assistant	100%
Jones	Anita	Research Nurse	100%
Lim	Sophie	Histology Technician	100%
Lisenby	Susan	Research Nurse	100%
Malady	Lori	Staff Research Nurse	100%
Means	Marilyn	Lead Medical Clerk/Receptionist	100%
Miller	Donald	Data Manager	100%
Minohar	Nallini	Research Assistant	100%
Moroni	Maria	Scientist	100%
O'Neill	Stacy	Research Nurse	100%
Overby	Julie	Receptionist	100%
Papay	Diane	Staff Research Nurse	100%
Pappas	Jennifer	Research Associate	100%
Park	Kathleen	Clinical Nurse Specialist	100%
Patterson	Carol	Medical Assistant	100%
Peoples	George	Breast Surgeon	25%
Ponniah	Sathibalan	Scientist-Immunologist	100%
Progar	Christina	Program Administrator	100%

Reece	Heike	Data Manager	100%
Reynolds	Paula	Research Nurse	100%
Rojas	Winifred	Lab Tech/Phlebotomist	100%
Rosenquist	Monica	Budget Analyst	100%
Russo	Jamie	Staff Research Nurse	100%
Salpeas	Veronica	Staff Research Nurse	100%
Sessoms	Lisa	Administrative Assistant	100%
Smith	Anna	Research Assistant	100%
Stojadinovic	Alexander	Breast Surgeon	25%
Storrer	Catherine	Senior Research Associate	100%
Thomas	Lisa	Health Tech / Procedure Room	100%
Williamson	Eric	Clinic Administrator	100%